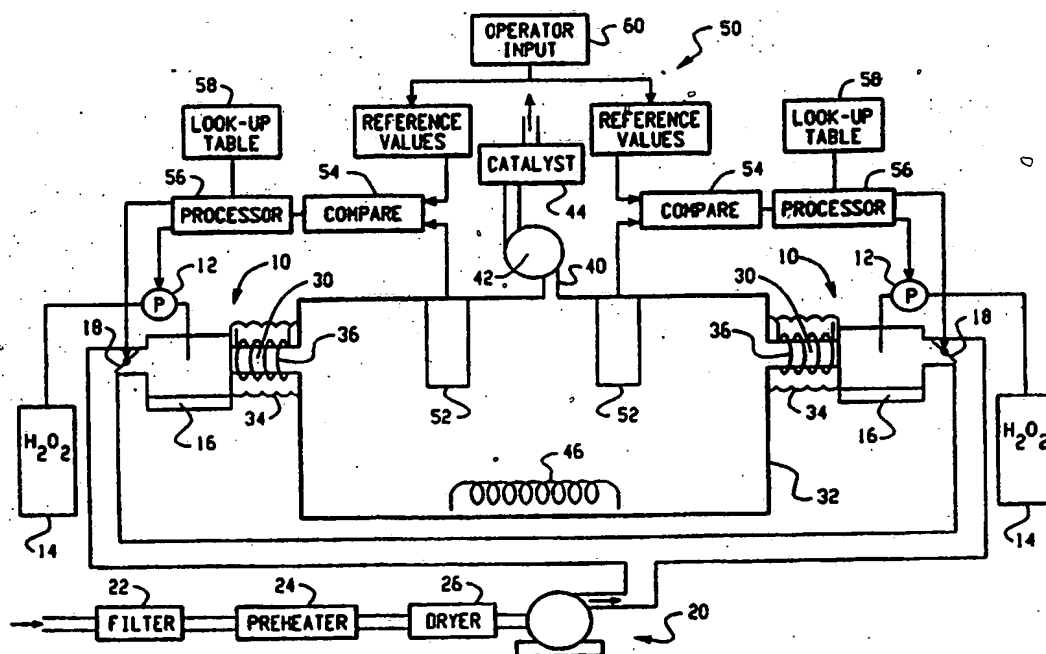




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(54) Title: MULTIPLE FLASHPOINT VAPORIZATION SYSTEM



(57) Abstract

A multiple flashpoint vaporization system rapidly sterilizes large enclosures. A plurality of vaporizers (10) inject hydrogen peroxide vapor into streams of carrier gas supplied by a generator (20). Supply lines (30) transport the mixture of carrier gas and hydrogen peroxide vapor to a plurality of regions of an enclosure (32). Monitors (52) monitor hydrogen peroxide vapor concentration or other conditions in each region of the enclosure. A control system (50) adjusts the hydrogen peroxide vapor supply rate in response to the corresponding monitored conditions.

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MULTIPLE FLASHPOINT VAPORIZATION SYSTEM

Background of the Invention

The present invention relates to the sterilization arts. It finds particular application in conjunction with hydrogen peroxide vaporization systems used in connection with the sterilization of large enclosures, and their contents, and will be described with particular reference thereto. It should be appreciated, however, that the invention is also applicable to other chemical vaporization systems such as peracetic acid vaporization systems.

Sterile enclosures are used by hospitals and laboratories for conducting tests in a microorganism-free environment. Processing equipment for pharmaceuticals and food, and freeze driers also include large enclosures which require sterilizing. Vaporized hydrogen peroxide is a particularly useful sterilant for these purposes because it is effective at low temperatures. Keeping the temperature of the enclosure near room temperature eliminates the potential for thermal degradation of associated equipment and items to be sterilized within the enclosure. In addition, hydrogen peroxide readily decomposes to water and oxygen, which, of course, are not harmful to the operator.

For effective sterilization, the hydrogen peroxide is maintained in the vapor state. Sterilization efficiency is significantly reduced by condensation. Many current hydrogen peroxide sterilizers inject a spray of hydrogen peroxide into a vacuum. The premier systems incorporate a single heated hydrogen peroxide vaporizer. A solution of about 35% hydrogen peroxide in water is injected into the vaporizer which heats

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it to form a vapor, without breaking it down to water and oxygen. A flow of air carries the vapor to the enclosure.

As the size of the enclosure increases, the demand for hydrogen peroxide is increased and the efficiency of the vaporization system becomes more significant. The capacity of the vaporizer is limited in a number of ways. First, the vaporization process creates a pressure drop, reducing the flow of air through the vaporizer. This increases the sterilization time and effectively limits the size of the enclosure to one which is capable of sterilization within an acceptable time period. Second, to maintain sterilization efficiency, the pressure at which the vapor is generated is limited to that at which the hydrogen peroxide is stable in the vapor state.

Further, large enclosures create problems themselves. Temperature differences throughout the chamber require different concentrations of the sterilant to compensate for condensation on cooler surfaces. Items within the enclosure require different concentrations of sterilant for optimum exposure because of their relative absorbencies. Pumping the vapor to more distant regions within the enclosure increases the extent of condensation within the vapor supply lines, reducing effectiveness. °.

One solution was to increase the size of the vaporizer and the injection rate of hydrogen peroxide into the vaporizer. Although helpful, the larger vaporizer still suffers from concentration variations and condensation concerns.

The present invention provides a new and improved vaporization system which overcomes the above referenced problems and others.

Summary of the Invention

In accordance with one aspect of the present invention, a hydrogen peroxide vaporization system is provided. The sterilization system includes a plurality of vaporizers for injecting hydrogen peroxide vapor into a carrier gas and a carrier gas generator for supplying a flow

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of carrier gas to the vaporizers. The system is characterized by at least one supply line for transporting the hydrogen peroxide vapor and the carrier gas from each vaporizer to different regions of an enclosure to be sterilized.

5 In accordance with another aspect of the present invention, a method of using the sterilization system for supplying vaporized hydrogen peroxide to an enclosure is provided. The method includes vaporizing a liquid solution of hydrogen peroxide to form hydrogen peroxide vapor at a first
10 and a second of the plurality of vaporizers, providing flows of carrier gas to the first and second of the plurality of vaporizers, and entraining the hydrogen peroxide vapor into the flows of carrier gas at the first and second of the plurality of vaporizers. The method is characterized by
15 independently transporting the hydrogen peroxide vapor and carrier gas from the first and second of the plurality of vaporizers to first and second of the different regions of the enclosure.

One advantage of the present invention is that
20 optimum sterilization throughout a large enclosure is achieved.

Another advantage is that sterilization is effected in a short period of time.

Another advantage of the present invention is that
25 the air flow and hydrogen peroxide injection rates can be increased.

Another advantage resides in improved hydrogen peroxide concentration uniformity.

Still further advantages of the present invention
30 will become apparent to those of ordinary skill in the art upon reading and understanding the following detailed description of the preferred embodiments.

Brief Description of the Drawings

35 The invention may take form in various components and arrangements of components, and in various steps and arrangements of steps. The drawings are only for purposes of

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illustrating a preferred embodiment and are not to be construed as limiting the invention.

The FIGURE is a cross section of a preferred embodiment of a hydrogen peroxide vaporization system in accordance with the present invention.

Detailed Description of the Preferred Embodiments

With reference to the FIGURE, a plurality of vaporizers 10 inject vaporized hydrogen peroxide into a carrier gas. More specifically, hydrogen peroxide is pumped, preferably by an adjustable metering pump 12 from a cartridge or reservoir 14 and injected at a measured rate in droplets or mist form onto a heated plate 16. The hydrogen peroxide vaporizes on contact with the plate and is entrained in a flow of the carrier gas. The temperature of the plate is maintained at a temperature below that at which dissociation of the hydrogen peroxide occurs. A carrier gas flow regulator or baffle 18 adjustably controls the flow of carrier gas. Adjusting the metering pump 12 and the carrier gas flow regulator 18 controls the rate at which the hydrogen peroxide vapor is produced.

The carrier gas is preferably air, although other gases which are unreactive toward hydrogen peroxide are also contemplated. A carrier gas generator 20, such as a pump or container of pressurized gas, supplies the carrier gas to the vaporizers 10. When atmosphere air is the carrier gas, filters 22 remove contaminants. Preferably, a preheater 24 raises the temperature of the carrier gas before it reaches the vaporizers 10, reducing condensation in the supply lines and raising the saturation concentration of hydrogen peroxide vapor. Optionally, a dryer 26 or the like controls the humidity of the carrier gas.

Supply lines 30 transport the mixture of carrier gas and vaporized hydrogen peroxide from the vaporizers 10 to an enclosure 32. To reduce the risk of condensation, the length of the supply lines 30 is minimized. To reduce the risk of condensation further, insulation 34 and/or heaters 36 surround the supply lines 30. Optionally, two or more supply lines

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connect each vaporizer to two or more regions of the enclosure 32.

A vent 40 permits controlled release of excess pressure in the enclosure. Optionally, vacuum pump 42 5 evacuates the enclosure prior to hydrogen peroxide vapor introduction. Evacuation increases the rate at which hydrogen peroxide vapor can be drawn into the chamber, reducing the supply pressure of the hydrogen peroxide vapor and thereby avoiding condensation. A catalyst 44 or the like breaks down 10 any residual hydrogen peroxide in the venter gas. Optionally, a heater 46 raises the temperature of and within the enclosure 32 prior to and during, sterilization. Raising the temperature in the enclosure or at least its surfaces also reduces vapor condensation.

15 Sterilizable enclosures include microorganism-free work areas, freeze dryers, and pharmaceutical or food processing equipment. Whether high sterilization temperatures and or evacuation of the enclosure during sterilization are feasible depends on the construction of the enclosure and the 20 nature of its contents. For example, sterilizable work areas are typically constructed of non-rigid plastic materials which do not withstand high temperatures and low pressures. Food processing equipment, in contrast, is often required to withstand high temperatures and pressures during processing 25 operations and is more easily adapted to achieving more optimal sterilization conditions through evacuation and heating.

Preferably the hydrogen peroxide concentration is 30-35% by weight aqueous hydrogen peroxide. At this level, 30 condensation of hydrogen peroxide is limited, while sterilization in a short period of time is achieved.

The hydrogen peroxide vapor is held in the enclosure 32 until sterilization is complete. Optionally, the vacuum pump 42 draws out the hydrogen peroxide vapor from the 35 enclosure following sterilization. This reduces the time required for dissipation of the hydrogen peroxide, and returns the enclosure to useful activity more quickly.

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In the illustrated embodiment, the vaporizers are located at a distance from the carrier gas generator, in close proximity to the enclosure. The rate of introduction of hydrogen peroxide by the individual vaporizers is adjustable
5 so as to optimize hydrogen peroxide vapor distribution within the enclosure.

Differences in temperature and absorbency of materials within the chamber, flow patterns in the chamber, and chamber shape are among the factors influencing the
10 optimum rate of introduction. Preferably a control system 50 regulates the introduction of hydrogen peroxide to the vaporizers in accordance with local conditions within the chamber. A plurality of monitors 52 monitor conditions within the enclosure 16. The monitors include temperature sensors,
15 humidity or vapor concentration sensors, air flow or turbulence sensors, pressure sensors, and the like. The control system includes a comparator 54 for comparing the monitored condition signals from the monitors with preselected ideal hydrogen peroxide vapor concentration and other
20 conditions as indicated by reference signals. Preferably, the comparator determines a deviation of each monitored condition signal from the corresponding reference signal or a reference value. Preferably, a plurality of the conditions are sensed and multiple comparators are provided. A processor 56
25 addresses a pre-programmed look up table 58 with each deviation signal (or combination of deviations of different conditions) to retrieve a corresponding adjustment for each vaporizer. Other circuits for converting larger deviations to larger adjustments and smaller deviations to smaller
30 adjustments are also contemplated. Alternately, the error calculation can be made at very short intervals with a constant magnitude increases or decreases when the monitored condition is below or above the reference points.

The adjustment values from the look up table adjust
35 the hydrogen peroxide metering pump 12 and the carrier gas regulator 18 to bring the monitored conditions to the reference values. For example, vapor injection rates are increased by vaporizers near regions with lower vapor

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concentration, lower temperatures, higher pressure, and the like. Vapor production rates are reduced in response to higher sensed vapor concentration, higher sensed temperatures, lower pressure, and the like. The processor, optionally, also
5 controls the chamber heater 46, circulation fans in the enclosure, the vacuum pump 42, or the like. Optionally, an operator input 60 enables the operator to adjust the reference signal in each region to cause higher or lower concentrations in selected regions.

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Having thus described the preferred embodiment, the invention is now claimed to be:

1. A hydrogen peroxide sterilization system
5 including a plurality of hydrogen peroxide vapor generators (10) for injecting hydrogen peroxide vapor into a carrier gas and a carrier gas generator (20) for supplying a flow of carrier gas to the vaporizers, characterized by:

10 at least one supply line (30) for transporting the hydrogen peroxide vapor and the carrier gas from each hydrogen peroxide vapor generator to different regions of a sterilization enclosure (32)..

2. The system as set forth in claim 1, further
15 characterized by:

the hydrogen peroxide vapor generators being remote from the carrier gas generator and being attached by individual supply lines to different regions of the enclosure.

20 3. The system as set forth in claim 1, further characterized by:

the hydrogen peroxide vapor generators being independently controlled to inject vaporized hydrogen peroxide
25 into the carrier gas at different rates.

4. The system as set forth in claim 1, further
characterized by:

each hydrogen peroxide vapor generator including a
stepper pump (12) for adjusting a supply rate of the liquid
30 hydrogen peroxide to a heated vaporizing surface (16).

5. The system as set forth in claim 1, further
characterized by:

each hydrogen peroxide vapor generator including a
35 liquid hydrogen peroxide regulator (50) for controlling a rate of injection of hydrogen peroxide to a heated vaporizing surface (16).

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6. The system as set forth in claim 5, further characterized by:

each hydrogen peroxide vapor generator further including a carrier gas flow regulator (18) for controlling a flow rate of carrier gas to the hydrogen peroxide vapor generator to regulate a concentration of hydrogen peroxide vapor.

7. The system as set forth in claim 1, further characterized by:

a plurality of monitors (52) for detecting conditions in each of the different regions of the enclosure; and,

each of the hydrogen peroxide vapor generators supplying hydrogen peroxide vapor to a different region of the enclosure.

8. The system as set forth in claim 7, further characterized by:

a control system (50) for regulating a rate at which hydrogen peroxide vapor is supplied by each hydrogen peroxide vapor generator in accordance with the conditions detected by the monitors (52) in each of the different regions of the enclosure.

9. A method of using the system of any of preceding claims 1-8 for supplying vaporized hydrogen peroxide to an enclosure comprising:

at a first of the plurality of hydrogen peroxide vapor generators (10), generating hydrogen peroxide vapor;

at a second of the plurality of hydrogen peroxide vapor generators (10), generating hydrogen peroxide vapor;

providing flows of carrier gas to the first and second of the plurality of hydrogen peroxide vapor generators;

entraining the hydrogen peroxide vapor into the flows of carrier gas at the first and second of the plurality of hydrogen peroxide vapor generators;

characterized by:

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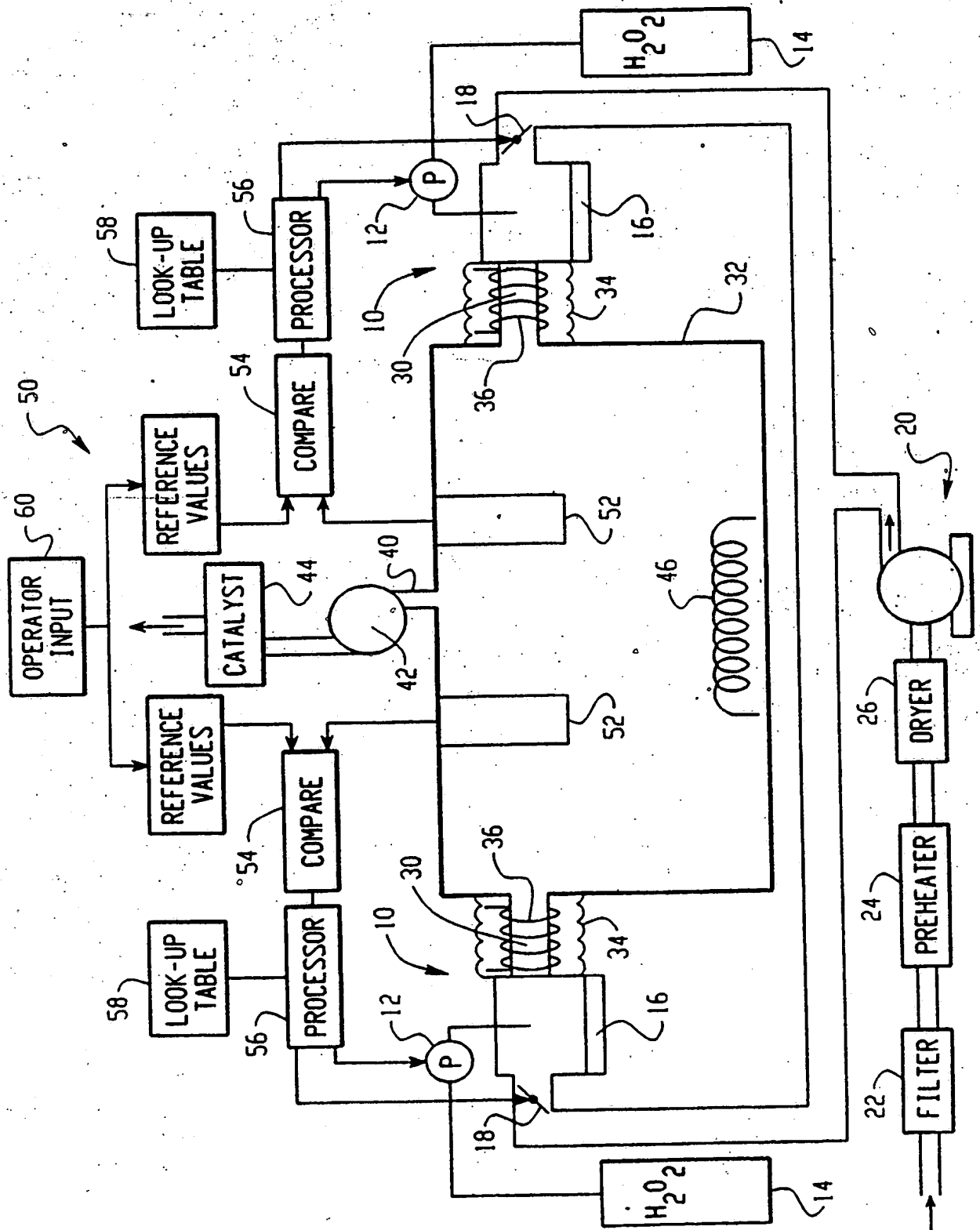
independently transporting the hydrogen peroxide vapor and carrier gas from the first and second of the plurality of hydrogen peroxide vapor generators to first and second of the different regions of the enclosure (32).

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10. The method as set forth in claim 9, further characterized by:

independently regulating a rate of vapor generation and entraining hydrogen peroxide vapor into the carrier gas.

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. tional Application No

PCT/US 98/08772

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9704816 A	13-02-1997	AU 6105496 A EP 0841955 A	26-02-1997 20-05-1998
EP 0774263 A	21-05-1997	GB 2308066 A	18-06-1997
EP 0197174 A	15-10-1986	JP 1713962 C JP 3074132 B JP 61234952 A US 4688585 A	27-11-1992 26-11-1991 20-10-1986 25-08-1987
WO 9007366 A	12-07-1990	US 5068087 A CA 2000815 A	26-11-1991 30-06-1990
WO 9105573 A	02-05-1991	US 5173258 A DE 69029660 D DE 69029660 T EP 0486623 A	22-12-1992 20-02-1997 24-04-1997 27-05-1992